

WHAT IS CLAIMED IS:

1. A pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin polymer composition isolated from a Croton spp. or from a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, formulated to protect the proanthocyanidin polymer composition from the stomach environment; and a pharmaceutically acceptable carrier.
2. The pharmaceutical composition of claim 1, in which the Croton spp. is *Croton lechleri*.
3. The pharmaceutical composition of claim 1, which further comprises an enteric coating.
4. The pharmaceutical composition of claim 3, in which the enteric coating is comprised of a methacrylic acid-methacrylic acid ester copolymer with acid ionizable groups.
5. The pharmaceutical composition of claim 4, which is formulated as a compressed tablet.
6. The pharmaceutical composition of claim 3, which is formulated as a capsule, which capsule is or is not enteric coated.
7. The pharmaceutical composition of claim 6, in which the capsule contains beads, each bead comprising a core of the proanthocyanidin polymer composition, and a layer of the enteric coating.
8. The pharmaceutical composition of claim 1, in which the proanthocyanidin polymer composition is protected from stomach acid.

9. The pharmaceutical composition of claim 1, in which the proanthocyanidin polymer composition is protected from the action of pepsin.

5 10. The pharmaceutical composition of claim 1, in which the proanthocyanidin polymer composition is formulated with a substance that inhibits the secretion of stomach acid.

11. The pharmaceutical composition of claim 1, in which
10 the proanthocyanidin polymer composition is formulated with a substance that neutralizes stomach acid.

12. A pharmaceutical composition comprising a therapeutically effective amount of a directly compressible
15 proanthocyanidin polymer composition isolated from a Croton spp. or from a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, and an enteric coating.

13. The pharmaceutical composition of claim 12, in
20 which the Croton spp. is *Croton lechleri*.

14. The pharmaceutical composition of claim 12, in which the enteric coating is comprised of a methacrylic acid-methacrylic acid ester copolymer with acid ionizable groups.
25

15. The pharmaceutical composition of claim 12, which is formulated as a compressed tablet.

16. The pharmaceutical composition of claim 12, which
30 further comprises a lubricant.

17. The pharmaceutical composition of claim 16, in which the lubricant is magnesium stearate.

35 18. The pharmaceutical composition of claim 12, which is formulated as a capsule, which capsule is or is not enteric coated.

19. The pharmaceutical composition of claim 18, in which the capsule contains beads, each bead comprising a core of the directly compressible proanthocyanidin polymer composition and a layer of the enteric coating.

5

20. A pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin polymer composition isolated from a *Croton* spp., or from a *Calophyllum* spp. or a pharmaceutically acceptable derivative thereof, which is formulated as a suppository in a pharmaceutically acceptable carrier.

21. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, a pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin polymer composition isolated from a *Croton* spp. or a *Calophyllum* spp., or a pharmaceutically acceptable derivative thereof, formulated to protect the proanthocyanidin polymer composition from the stomach environment, and a pharmaceutically acceptable carrier.

22. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, a pharmaceutical composition comprising a therapeutically effective amount of a directly compressible proanthocyanidin polymer composition isolated from a *Croton* spp. or from a *Calophyllum* spp., or a pharmaceutically acceptable derivative thereof, and an enteric coating.

23. The method of claim 22, in which the *Croton* spp. is *Croton lechleri*.

35

24. The method of claim 22, in which the enteric coating is comprised of a methacrylic acid-methacrylic acid ester copolymer with acid ionizable groups.

5 25. The method of claim 22, in which the pharmaceutical composition is formulated as a compressed tablet.

26. The method of claim 22, in which the pharmaceutical composition further comprises a lubricant.

10

27. The method of claim 26, in which the lubricant is magnesium stearate.

28. The method of claim 22, in which the pharmaceutical
15 composition is formulated as a capsule, which capsule is or is not enteric coated.

29. The method of claim 28, in which the capsule
contains beads, each bead comprising a core of the directly
20 compressible proanthocyanidin polymer composition and a layer of the enteric coating.

30. The method of claim 22, in which the diarrhea is caused by a bacterium.

25

31. The method of claim 22, in which the secretory diarrhea is caused by a non-infectious etiology.

32. The method of claim 31, in which the non-infectious
30 etiology is selected from the group consisting of non-specific diarrhea, ulcerative colitis, inflammatory bowel syndrome, and cancers and neoplasias of the gastrointestinal tract.

33. The method of claim 22, in which the human
35 suffering from diarrhea is an infant or a child.

34. The method of claim 22, in which a human is treated for HIV-Associated Chronic Diarrhea.

35. The method of claim 22, in which a human is treated 5 for cholera.

36. The method of claim 22, in which a non-human animal is treated for secretory diarrhea.

10 37. The method of claim 36, in which the non-human animal is selected from the group consisting of bovine animals, swine, ovine animals, poultry, equine animals, canine animals and feline animals.

15 38. The method of claim 36 in which the pharmaceutical composition is delivered in animal feed.

39. The method of claim 23, in which the pharmaceutical composition is delivered orally.

20

40. The method of claim 39, in which the human or non-human animal is given between 0.1 and 40 mg/kg per day of the proanthocyanidin polymer composition.

25 41. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, a pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin polymer composition
30 isolated from a Croton spp. or a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, which is formulated as a suppository for rectal administration in a pharmaceutically acceptable carrier.

35 42. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, (a) a

first pharmaceutical composition comprising a therapeutically effective amount of a proanthocyanidin polymer composition isolated from a Croton spp. or a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, and a
5 pharmaceutically acceptable carrier; and (b) a second pharmaceutical composition comprising an amount effective to inhibit stomach acid secretion of a compound effective to inhibit stomach acid secretion, and a pharmaceutically acceptable carrier.

10

43. The method of claim 42, in which said first pharmaceutical composition is administered at a time subsequent to the administration of said second
15 pharmaceutical composition but during the period of inhibition of stomach acid secretion.

44. The method of claim 42, in which said first pharmaceutical composition is administered concurrently with said second pharmaceutical composition.

20

45. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, (a) a first pharmaceutical composition comprising a therapeutically
25 effective amount of a proanthocyanidin polymer composition isolated from a Croton spp. or a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, and a pharmaceutically acceptable carrier; and (b) a second pharmaceutical composition comprising an amount effective to
30 neutralize stomach acid of a compound effective to neutralize stomach acid, and a pharmaceutically acceptable carrier.

46. The method of claim 45, in which said first pharmaceutical composition is administered at a time
35 subsequent to the administration of said second pharmaceutical composition but during the period in which the stomach acid is neutralized.

47. The method of claim 45, in which said first pharmaceutical composition is administered concurrently with said second pharmaceutical composition.

5 48. A method of preventing secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human at risk of developing diarrhea, a pharmaceutical composition comprising a prophylactically effective amount of a proanthocyanidin polymer composition
10 isolated from a Croton spp. or a Calophyllum spp., or a pharmaceutically acceptable derivative thereof, formulated to protect the proanthocyanidin polymer composition from the stomach environment; and a pharmaceutically acceptable carrier.

15 49. The method of claim 48, in which the proanthocyanidin polymer composition is formulated with a substance that inhibits the secretion of stomach acid.

20 50. The method of claim 48, in which the proanthocyanidin polymer composition is formulated with a substance that neutralizes stomach acid.

51. A method of preventing secretory diarrhea in
25 animals, including humans, comprising: administering, to a non-human animal or human at risk of developing diarrhea, a pharmaceutical composition comprising a prophylactically effective amount of a directly compressible proanthocyanidin polymer composition isolated from a Croton spp. or from a
30 Calophyllum spp., or a pharmaceutically acceptable derivative thereof, and an enteric coating.

52. The method of claim 51, in which the Croton spp. is *Croton lechleri*.

35

53. The method of claim 51, in which the enteric coating is comprised of a methacrylic acid-methacrylic acid ester copolymer with acid ionizable groups.

5 54. The method of claim 51, in which the pharmaceutical composition is formulated as a compressed tablet.

55. The method of claim 51, in which the pharmaceutical composition further comprises a lubricant.

10

56. The method of claim 55, in which the lubricant is magnesium stearate.

57. The method of claim 51, in which the pharmaceutical
15 composition is formulated as a capsule, which capsule is or is not enteric coated.

58. The method of claim 57, in which the capsule
20 contains beads, each bead comprising a core of the directly compressible proanthocyanidin polymer composition and a layer of the enteric coating.

59. The method of claim 51, in which the diarrhea is caused by a bacterium.

25

60. The method of claim 51, in which the secretory diarrhea is caused by a non-infectious etiology.

61. The method of claim 60, in which the non-infectious
30 etiology is selected from the group consisting of non-specific diarrhea, ulcerative colitis, inflammatory bowel syndrome, and cancers and neoplasias of the gastrointestinal tract.

35 62. The method of claim 51, in which the human suffering from diarrhea is an infant or a child.

63. The method of claim 51, in which a human is treated for HIV-Associated Chronic Diarrhea.

64. The method of claim 51, in which a human is treated 5 for cholera.

65. The method of claim 51, in which a non-human animal is treated for secretory diarrhea.

10 66. The method of claim 65, in which the non-human animal is selected from the group consisting of bovine animals, swine, ovine animals, poultry, equine animals, canine animals and feline animals.

15 67. The method of claim 65, in which the pharmaceutical composition is delivered in animal feed.

68. The method of claim 51, in which the pharmaceutical composition is delivered orally.

20

69. The method of claim 68, in which the human or non-human animal is given between 0.1 and 40 mg/kg per day of the proanthocyanidin polymer composition.

25 70. A method for isolating a directly compressible proanthocyanidin polymer composition comprising:

- (a) extracting an aqueous solution of latex from *Croton lechleri* with n-butanol;
- 30 (b) concentrating the aqueous phase of the extracted latex solution by ultrafiltration to produce a retentate;
- (c) chromatographing the retentate of step b on a CM-Sepharose column in an acetone solution;
- 35 (d) chromatographing the product of step c on an LH-20 column in an acetone solution;
- (e) collecting fractions from the LH-20 column; and

(f) pooling the fractions collected from the column in step d that contain material with detectable absorbance at 460 nm.

5 71. A pharmaceutical composition comprising the directly compressible proanthocyanidin polymer composition produced by the method of claim 70; and an enteric coating.

72. The pharmaceutical composition of claim 71, which
10 further comprises a lubricant.

73. A method of treatment for secretory diarrhea in animals, including humans, comprising: administering, to a non-human animal or human suffering from diarrhea, a
15 therapeutically effective amount of the pharmaceutical composition of claim 71.

74. A method of preventing secretory diarrhea in animals, including humans, comprising: administering, to a
20 non-human animal or human at risk of developing diarrhea, a prophylactically effective amount of the pharmaceutical composition of claim 71.

25

30

35